

[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed collection; 60-day comment request

Application for Collaboration with the Therapeutic Development Branch (TDB),

Division of Preclinical Innovation (DPI), National Center for Advancing Translational

Sciences (NCATS)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Center for Advancing Translational Sciences (NCATS), National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the

1

burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

TO SUBMIT COMMENTS AND FOR FURTHER INFORMATION: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Nora Yang, Therapeutic Development Branch, DPI, NCATS, NIH, 9800 Medical Center Drive, Building B, Rockville, MD 20850, or call non-toll-free number (301) 217-1077, or E-mail your request, including your address to: TRND@mail.nih.gov Formal requests for additional plans and instruments must be requested in writing.

COMMENT DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

PROPOSED COLLECTION: Application for Collaboration with the Therapeutic Development Branch (TDB), Division of Preclinical Innovation (DPI), National Center for Advancing Translational Sciences (NCATS), 0925-0658, Expiration Date 06/30/2015 - EXTENSION, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health (NIH).

Need and Use of Information Collection: The Therapeutic Development Branch (TDB) provides opportunities to partner with and gain access to a variety of programs

delivering assay development, screening, hit-to-lead chemistry, lead optimization, chemical biology studies, drug development capabilities, expertise, and clinical/regulatory resources in a collaborative environment, with the goal of moving promising therapeutics into human clinical trials for both common and specifically rare and/or neglected diseases. The TDB uses an application and evaluation process to select collaborators. Selected investigators provide the drug project starting points and ongoing biological/disease expertise throughout the project. The application and evaluation process is necessary to determine amount and quality of current data, select meritorious projects for adoption, and to serve as a basis for determining specific scientific gaps to be filled.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The estimated annualized burden hours are 510.

Estimated Annualized Burden Hours

Form Name	Number	Number of	Average	Total
	of	Responses	Burden	Annual
	Respondents	per	Per	Burden
		Respondent	Response	Hour
			(in hours)	
TDB Project	170	1	1	170
Information				
Template				
Online	100	1	1	100
Collaborator				
Solicitation				
(TRND)				
Online	70	1	1	70
Collaborator				
Solicitation				
(BrIDGs)				

Solicitation	100	1	1	100
Instructions				
(TRND)				
Solicitation	70	1	1	70
Instructions				
(BrIDGs)				

Dated: October 29, 2014

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NCATS, NIH

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